

US009636403B2

(12) United States Patent

Albert et al.

(10) Patent No.: US 9,636,403 B2

(45) **Date of Patent:** May 2, 2017

(54) COMPOSITION FOR THE TREATMENT OF EAR INFECTIONS AND METHOD

- (75) Inventors: Rory J Albert, Scottsdale, AZ (US); Michael R. Blaire, Scottsdale, AZ (US)
- (73) Assignee: **Diamondback Drugs of Delaware,** L.L.C., Scottsdale, AZ (US)
- (*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 964 days.
- (21) Appl. No.: 13/195,194
- (22) Filed: Aug. 1, 2011

(65) Prior Publication Data

US 2011/0281833 A1 Nov. 17, 2011

Related U.S. Application Data

- (62) Division of application No. 10/830,548, filed on Apr. 23, 2004, now Pat. No. 8,003,616.
- (51) Int. Cl.

 A61K 31/56 (2006.01)

 A61K 45/06 (2006.01)

 A61K 31/4709 (2006.01)

 A61K 31/496 (2006.01)

 A61K 31/704 (2006.01)

 A61K 31/7048 (2006.01)
- (52) U.S. Cl.
 CPC A61K 45/06 (2013.01); A61K 31/4709
 (2013.01); A61K 31/496 (2013.01); A61K
 31/704 (2013.01); A61K 31/7048 (2013.01);
 A61K 31/56 (2013.01)

(56) References Cited

U.S. PATENT DOCUMENTS

4,569,935 A *	2/1986	Rosenberg et al 514/254.07
5,753,269 A	5/1998	Groh et al.
5,837,713 A *	11/1998	Gleich 514/312
6,126,920 A *	10/2000	Jones et al 424/45

FOREIGN PATENT DOCUMENTS

EP 0179583 A1 4/1986

OTHER PUBLICATIONS

Lipsky et al. Int. J. Dermatol., 1992, vol. 31, Iss. 6, abstract.* Erowid Alcohol Vault. Alcohol Chemistry, Published online Nov. 1999, pp. 1-2.*

Freedom of Information Summary, ANADA 200-287, GBC Ointment, Phoenix Scientific, Inc., Mar. 28, 2003, pp. 1-4.

Freedom of Information summary, NADA 141-177, MOMETAMAX Otic Suspension for dogs, Schering-Plough Animal Health, Publication date not known, but published prior to Apr. 2003, 13 pages.

"Medical Treatment of Otitis Externa", Stephen White, Publication date now known, but published before Apr. 2003, 6 pages.

Lecture Notes, Jan. 2003 Dermatology, Daniel O. Morris, D.V.M., District of Columbia Academy of Veterinary Medicine, "Otitis Externa and Media: Diagnosis and management in the age of antibiotic resistance", Jan. 2003, 7 pages.

Freedom of Information summary, NADA 140-810, Feb. 3, 1989, Biomed laboratories, Panavet Ointment, 4 pages.

Product labeling for Otomax Otic Antibiotic-Steroid, NADA 140-896, Schering-Plough, Publication date not known, but published before Apr. 2003, 3 pages.

Baytril Otic, product information by Bayer Health Care, Animal Health Division, original publication date not known, but published prior to Apr. 2003, 3 pages.

Jan. 2001 Press Release for Baytril Otic, dated Jan. 2001, 2 pages. Baytril Otic product labeling, Bayer health Care LLC, Animal Health Division, publication date not known, but originally published prior to Apr. 2003, 4 pages.

"Introduction to Pharmaceutical Dosage Forms", Howard C. Ansel, Lea & Febiger, 4th Edition, 1985, pp. 337-341.

"The Science and Practice of Pharmacy", Troy, D.B., Ed. Remington, Lippincott Williams & Wilkins, 21st Edition, 2006, pp. 1080-1082.

* cited by examiner

Primary Examiner — Samira Jean-Louis (74) Attorney, Agent, or Firm — Cahill Glazer PLC

(57) ABSTRACT

A composition for treating ear infections in animals includes an antifungal agent, an antibiotic agent, a steroidal anti-inflammatory agent, and an acid dissolved to form a liquid. The acid aids in keeping the steroidal anti-inflammatory agent in solution, and enhances the bactericidal effect of the composition. The method of preparing such composition includes dissolving the antifungal agent, steroidal anti-inflammatory agent, and acid in dehydrated alcohol, dissolving the antibiotic agent in propylene glycol, combining the two solutions together, heating the combination and then cooling the composition. Several drops of the composition are applied at least twice per day to the affected area of the animal's ear.

13 Claims, No Drawings